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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,526

02/08/2006

Robert E Dudley

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7590

11/17/2008

MAYER BROWN LLP  
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EXAMINER

HUI, SAN MING R

ART UNIT

PAPER NUMBER

1617

NOTIFICATION DATE

DELIVERY MODE

11/17/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@mayerbrown.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/531,526	<b>Applicant(s)</b> DUDLEY, ROBERT E	
	<b>Examiner</b> San-ming Hui	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/8/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's amendments filed July 17, 2008 have been entered.

Claims 1-51 are pending.

In view of the amendments filed July 17, 2008, the outstanding rejections under 35 USC 102(e) and 103(a) are withdrawn.

New ground of rejection is set forth below:

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added limitation "that excludes all of the known compounds that inhibits ... derivatives of these compounds" recited in claim 1 is not supported by the originally filed specification or the originally filed claims. Such exclusion is considered as new matter. The applicant is required to cancel the new matter.

#### ***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO02/17926 ('926) and Hussain et al. (US 6,200,591, reference of record).

'926 teaches the use of Androgel® - testosterone in hydroalcoholic gel with isopropyl myristate as effective in increase libido, mood, and sexual function, especially in patient suffered from hypogonardism (See the abstract, claims 5, 8, page 61-65 for example). '926 also teaches the herein claimed concentration of testosterone and the ingredients of the testosterone gel (See claim 8 for example).

Hussain et al. teaches the method of intranasal administration of sildenafil citrate to treat erectile dysfunction (See abstract, Figure 1; col 2, lines 58-64; col. 10, Example 2 or 3), which may additionally include other pharmaceutical agents such as apomorphine, papaverine, phentolamine and phenoxybenzamine (See col. 3, lines 23-28; col. 10, Example 4 or 5). Administration of one spray into each nostril will deliver a total of 30mg of sildenafil HCl and apomorphine HCl (See col. 10, example 4). Hussain et al also teaches the combination therapies that use sildenafil and apomorphine or other pharmaceutical agents such as papaverine, phentolamine and phenoxybenzamine may be administered simultaneously or sequentially in separate formulations to reach a combined effect (See col. 3, lines 26-28; col. 8, lines 3-12).

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The references do not expressly teach the use of the testosterone gel and sildenafil and other active agents together in a method of increasing sexual performance. The references do not expressly teach the dosage of sildenafil.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the agents/composition, in the dosage herein claimed, taught in '926 and Hussain et al. together in a method of increasing sexual performance.

One of ordinary skill in the art would have been motivated to employ the agents taught in '926 and Hussain et al. together in a method of increasing sexual performance. Combining two agents which are known to be useful to increase performance (by either treating erectile dysfunction or increasing libido and sexual function) individually into a single composition useful for the very same purpose is prima facie obvious (See *In re Kerkhoven* 205 USPQ 1069 (CCPA 1980)). Furthermore, the optimization of the result parameter (e.g., dosage and dosing regimen) is considered to be obvious as being within the purview of skilled artisan.

No claims are allowed.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-51 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon - Fri from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui  
Primary Examiner  
Art Unit 1617

/San-ming Hui/  
Primary Examiner, Art Unit 1617